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Fujinon Medical Hygiene

Reprocessing of flexible endoscopes and endoscopic accessories.

For perfect hygiene in endoscopy.

As one of the leading manufacturers of flexible endoscopes, we are very conscious of our responsibility towards you and your patients. For this reason we would like to support you in all the important aspects regarding the perfect reprocessing of endoscopes and endoscopic accessories.

Hygiene is the number one priority in hospitals and doctors' practices. It provides protection against the transmission of germs and prevents infections in patients, doctors and nursing staff. With this brochure, Fujinon provides you with a useful guide to the simple and reliable cleaning and disinfecting of your endoscope, making your everyday working life easier.

The hygiene brochure is divided chronologically. It takes you step by step through the individual procedures: from preliminary cleaning through to final rinsing. Each individual action is therefore easy to understand, using photographs for illustration. In addition, the brochure provides you with important product summaries and helpful practical tips.

It goes without saying that all the procedures described here comply with the guidelines of the Robert Koch Institute (RKI) entitled "Hygiene requirements in the reprocessing of flexible endoscopes and additional endoscopic equipment". Together with the high-quality products from Fujinon, you can thus ensure the optimum conditions for reliable diagnoses and treatments.

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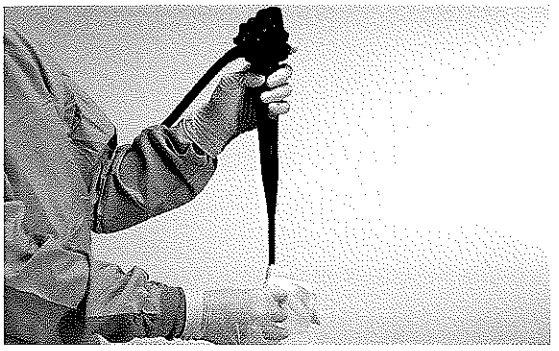
Manual reprocess

1. Step: Preliminary cleaning

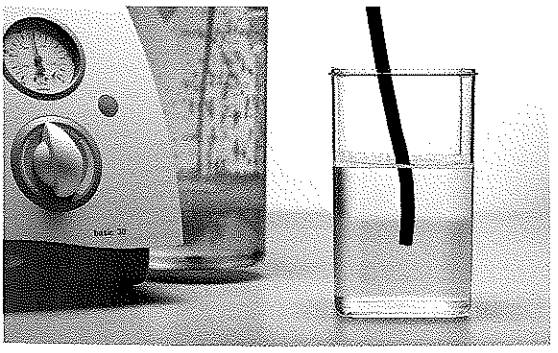
1.1 The preliminary cleaning is carried out immediately following the examination.

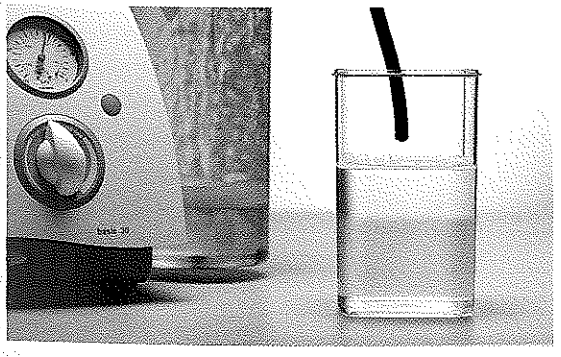
1.2 Wipe the outer surface of the endoscope with a disposable cloth or damp compress (cleaning solution).



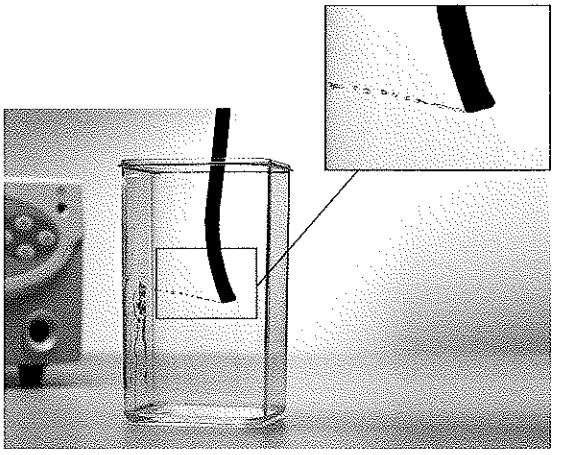
1.3 Hold the distal end of the endoscope in a container with cleaning solution.

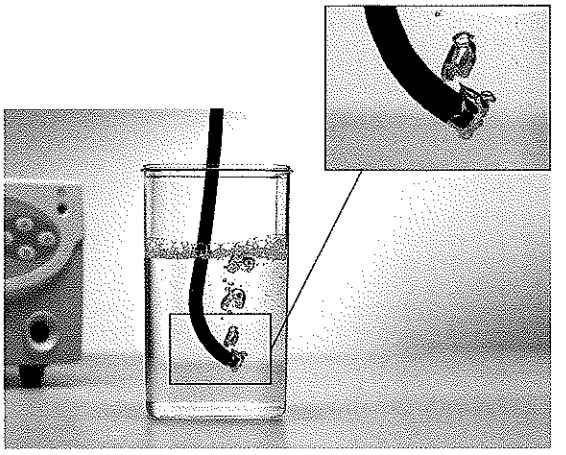
1.4 Thoroughly rinse the channels:
- Activate the suction valve until the solution is clear.
- Alternate drawing in cleaning solution and air.





- Activate the air/water valve and pay attention to the escaping jet of water and bubbles.

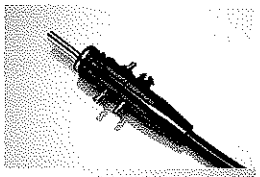




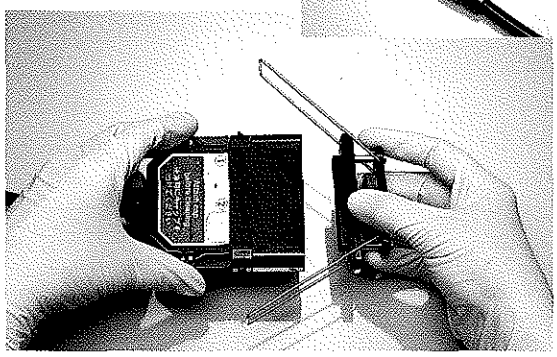
⚠ With the duodenoscope and ultrasound endoscope with Albarran lever, the lever must be moved several times during preliminary cleaning.

1.5 Take the distal end out of the cleaning solution and thoroughly suction the channels.
- Suction the outlet channel with air until empty.
- Separate the water tank from the endoscope.
- Place a finger on the water tank attachment and activate the air/water valve until the flow of water stops.
- Disconnect the device from the processor/light source with a cloth.

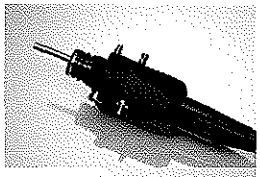
1.6 Attach the protective cap for electronic plugs with video endoscopes.



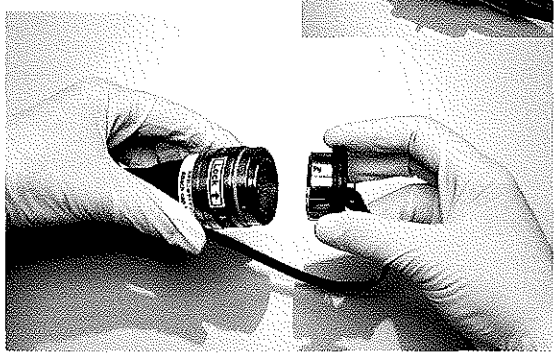
EVE Series 200 supply plug



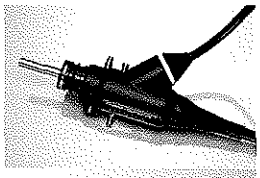
EVE Series 200 electronic plug



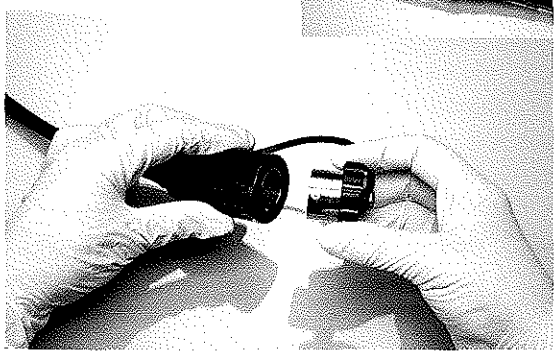
EVE Series 400 supply plug



EVE Series 400 electronic plug



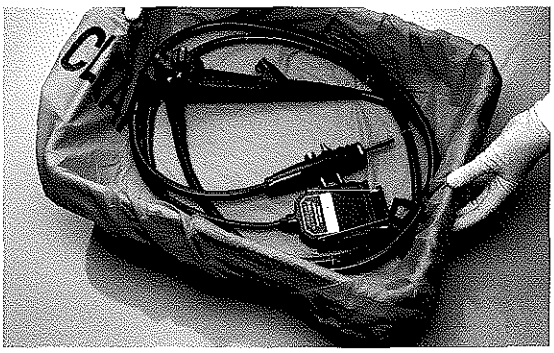
EVE Series 500 supply plug



EVE Series 500 electronic plug

1.7 Place the endoscope in a closed transporting bowl.

⚠ Take care that the effect of heat from the optical light-guide connector will not damage the endoscope!



Contaminated endoscope

1.8 Take the endoscope to the reprocess room.

Contaminated endoscope

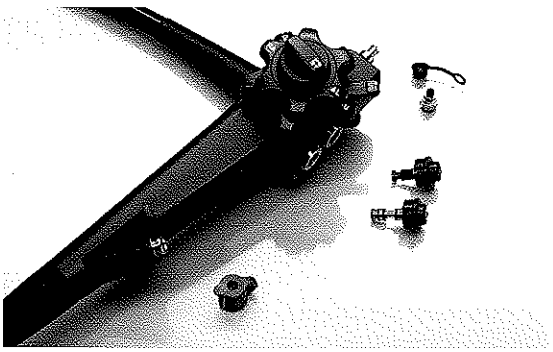
2. Step: Leak test

2.1 Carry out a leak test under water in accordance with the manufacturer's instructions.

2.2 Always pump up the endoscope to 150 mmHg before placing in the solution.

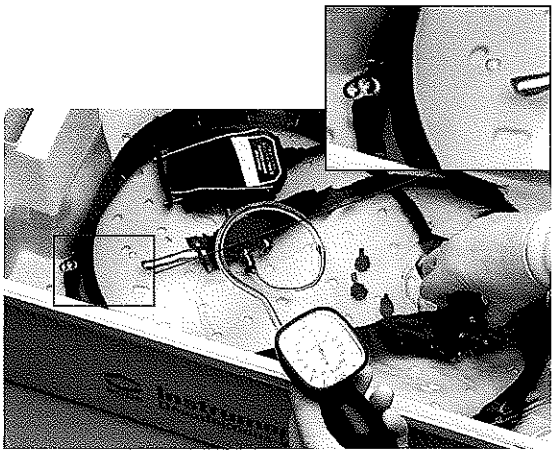
⚠ Never connect and disconnect the leak tester in the water.

2.3 Remove all valves (air/water and suction valves, as well as the distal cap and jet channel closing cap) and place in the solution. The disposable biopsy valve must be properly disposed of after each use.



2.4 Place the endoscope in a basin with the cleaning solution.

2.5 Activate the bending wheels and pay attention to areas that leak (rising bubbles). In addition, examine the manometer for any drop in pressure.



LT-7

⚠ If it is clear there is perforation, do not proceed further with reprocessing the endoscope.

2.6 Wipe the outer surface with disinfecting solution. Wrap the endoscope in a protective foil cover, pack in the despatch case, mark with „leaking, not disinfected" and a description of the fault and send to the maintenance and repair shop.

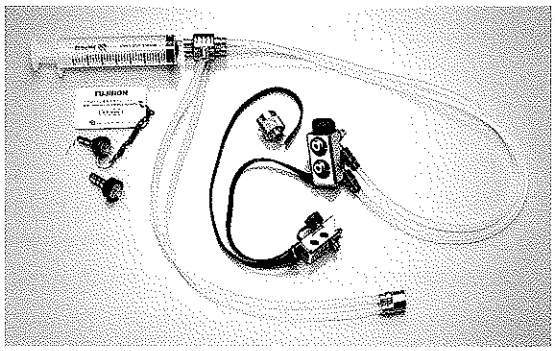
2.7 After repair, carry out a leak test and clean and disinfect the endoscope.

3. Step: Manual cleaning with a brush

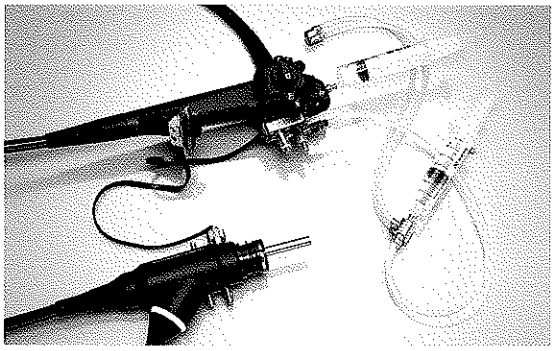
3.1 For reasons of personal safety, carry out all cleaning procedures under the surface of the liquid.

3.2 Clean the surface of the endoscope with a lint-free cloth.

3.3 Using the CA-503A set, fill all channels with cleaning solution so that there are no bubbles.

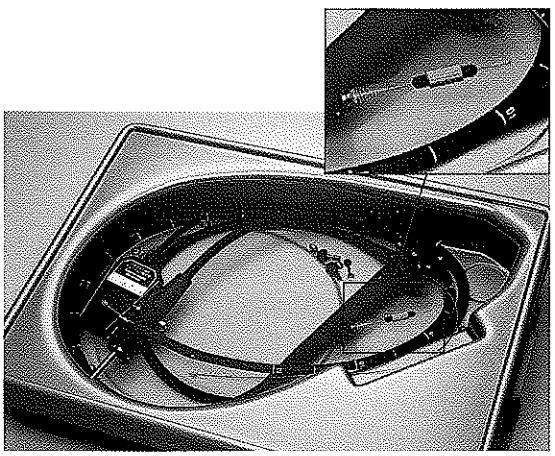


CA-503A / CA-500N / CA-300N

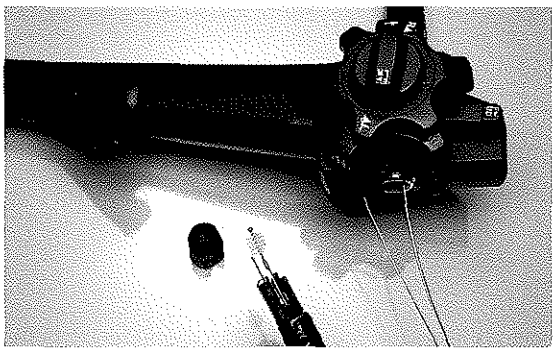


CA-503A

3.4 Clean the biopsy channel, valve openings and valves with a double valve cleaning brush.

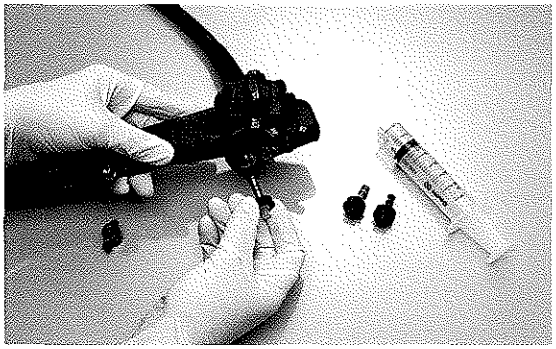


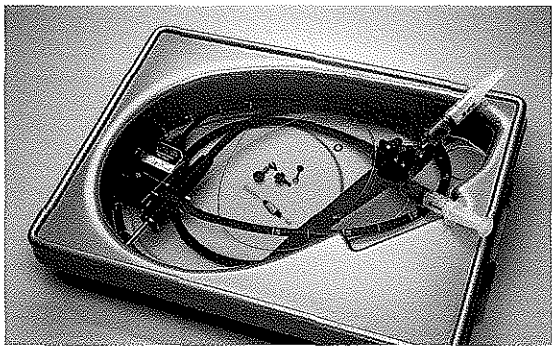
3.5 In the case of duodenoscopes, move the Albarran lever to *the middle position and clean from all sides with a suitable* brush.



With the G8 series, the air/water channel can be cleaned separately with a brush. The WA-500 (guide for the cleaning brush) is needed for this.

3.6 Clean all accessible channel systems with a suitable endoscope brush until the brushes can be pushed through free of contaminants.





3.7 In the case of channel which are not be cleaned with brushes, *e.g.* the air/water channel, jet channel, lens rinse channel, balloon air feed channel with the double balloon endoscope (DBE) and balloon water feed channel with the ultrasound endoscopes (EG-530UR and EG-530UT), connect to *device-specific adapters and rinse thoroughly with solution.* The CJ-500 is the cleaning adapter for the jet channel with the G5 endoscopes and the balloon water feed channel with the ultrasound endoscopes. The CA-300N and CA-500N *are cleaning adapters for the air/water channel.*

⚠ In case of the G8 duodenoscopes, the air/water channel can also be cleaned with a brush. With the EG-530UT ultrasound endoscope, the balloon water feed channel can also be cleaned with a brush.

⚠ Steps 1 to 3 are identical with manual, semi-automatic machine and machine reprocess.

4. Step: Intermediate rinsing

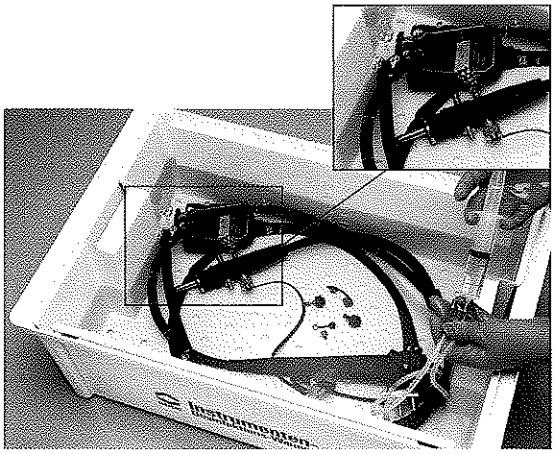
4.1 Place the endoscope and valves in a basin with microbiologically clean drinking water or sterile water in order to remove residues of chemicals, blood, protein and medication.

4.2 Using the CA-503A set or a water gun, thoroughly rinse all channels and then remove all remaining water with air. Always rinse separately the jet channel and balloon air feed channel and balloon water feed channel and likewise remove remaining water.

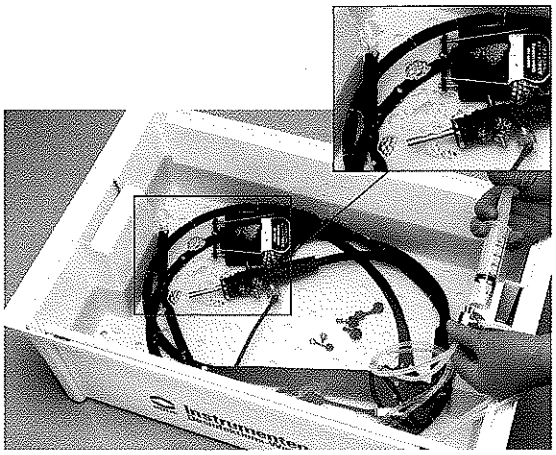
5. Step: Disinfection

5.1 Place the cleaned endoscope and valves in the disinfection solution. Connect the CA-503A set and fill until there are no bubbles.

5.2 Connect the jet channel, lens rinsing channel, and air and water supply channels to device-specific adapters and/or fill with syringes. Use the CJ-500 cleaning adapter for the jet channel and the balloon water feed channel. In the case of the duodenoscope and ultrasound endoscope move the Albarran lever to the middle position.



Suction/entry supports and distal end (red coding)



Air channel and distal end (blue coding)

5.3 Ensure concentration and residence time complies with the manufacturer's instructions.

5.4 For reasons of personal safety, close the bowl tightly with the cover.

5.5 At the end of the disinfection time, fill the channels with air to remove the disinfectant.

5.6 Using new disposable gloves, remove the endoscope from the disinfectant solution.

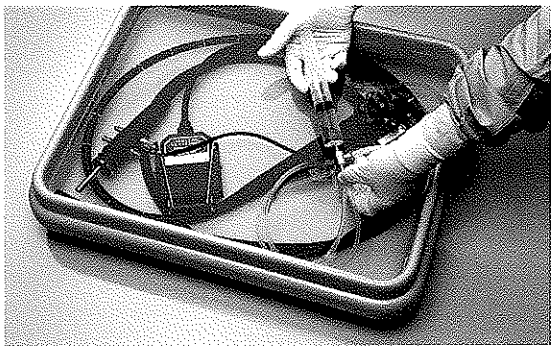
6. Step: Final rinsing

6.1 Place the endoscope and valves in a disinfected bowl with microbiologically clean drinking water or sterile water.

⚠ **Fresh water should be used for each device.**

6.2 Rinse out the outer endoscope surface and valves.

6.3 Thoroughly rinse all the channels with the CA-503A and device-specific adapters or a water gun with sterile filter.



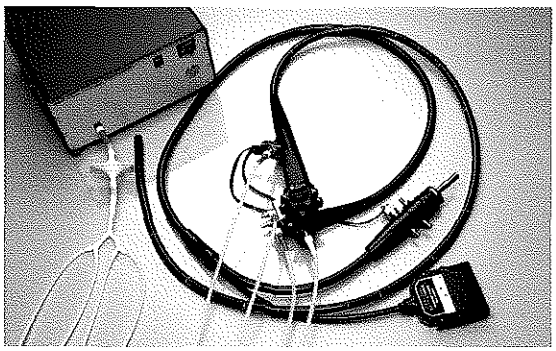
7. Step: Drying and storage

7.1 Remove the endoscope and valves with disinfected hands or wearing new disposable gloves.

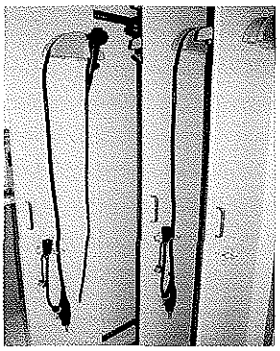
7.2 With a lint-free cloth, remove any water remaining on endoscope surface, operating section and valves.

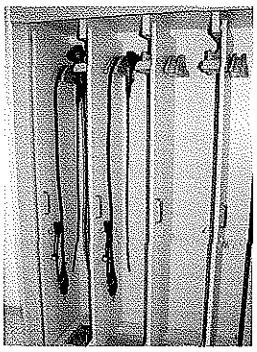
7.3 *Air the electrical contacts and channels with a compressed* air gun or, using a connector set, connect the endoscope to a compressor for approx. 20 minutes (maximum pressure 0.7 bar).

⚠ *The following is important with the double balloon endoscope:* the water in the balloon air feed channel must be completely removed because this channel must be completely dry.



7.4 The preferred method of storing the endoscope is hanging up in a special endoscope cabinet in a dry environment protected from dust and with suitable fasteners.





7.5 During storage of the endoscope, the valves and protective cap for the electronic plug must be removed and stored separately.

8. Step: Reprocessing of work materials

8.1 The date the disinfectant solution was prepared must be documented.

8.2 Label on the bowl: date, concentration, residence time, service life of the disinfectant solution.

8.3 The disinfectant solution must be replaced in accordance with the manufacturer's instructions.

8.4 Ensure concentration and residence time comply with the manufacturer's instructions.

8.5 When replacing the cleaning solution (manual cleaning with a brush), the bowl must be thoroughly cleaned and disinfected mechanically.

8.6 Used brushes must be cleaned in an ultrasound bath, rinsed, disinfected, final rinsed and dried after each use.

8.7 See page 11 for reprocess of accessories.

Machine reprocess

⚠ The following steps must also be carried out in advance of machine reprocess in an AWD (Automatic Washer Disinfector for endoscopes):

1. Step: Preliminary cleaning

2. Step: Leak test

3. Step: Manual cleaning with a brush

Steps 1 to 3 are identical with manual reprocess. See pages 3 to 6.

4. Step: Intermediate rinsing/rinsing of the cleaning solution

4.1 Place the endoscope and valves in a basin with microbiologically clean drinking water or sterile water in order to remove residues of chemicals, blood, protein and medication.

4.2 Rinse all channels using the CA-503A set or with a water gun.

⚠ Please note that in accordance with AWD manufacturer instructions the intermediate rinsing can be replaced by the machine preliminary cleaning phase.

⚠ Caution: insufficient intermediate rinsing can cause interactions when at the same time using aldehyde-free chemicals in the preliminary cleaning/manual cleaning with a brush steps and chemicals containing aldehyde in the machine.

5. Step: Disinfection

5.1 In accordance with the machine manufacturer's instructions, place the cleaned endoscope and valves in the Automatic Washer Disinfector for endoscopes (AWD).

5.2 Connect the appropriate connector set and leak tester.

5.3 Select the appropriate programme, preferably the standard programme.

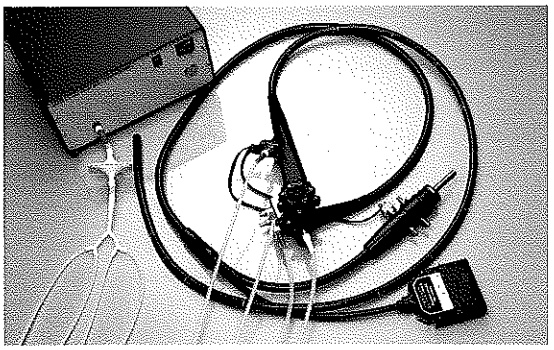
5.4 Start the programme.

6. Step: Drying and storage

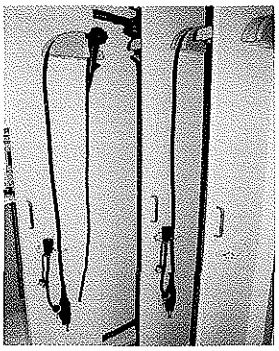
6.1 Remove the endoscope and valves from the AWD with disinfected hands or wearing new disposable gloves.

6.2 With a lint-free cloth, remove any water remaining on the outer surface, actuator and valves.

6.3 Air the electrical contacts and channels with a compressed air gun or, using a connector set, connect the endoscope to a compressor for approx. 20 minutes (maximum pressure 0.7 bar).



6.4 The preferred method of storing the endoscope is hanging up in a special endoscope cabinet in a dry environment protected from dust and with suitable fasteners.



6.5 During storage of the endoscope, the valves and protective cap for the electronic plug must be removed and stored separately.

7. Step: Reprocess of work materials

7.1 A self-disinfecting cycle is recommended before using the AWD each day.

7.2 The containers for the cleaning and disinfecting agents must be marked with the date of opening.

7.3 Replace the water filters and air filters in accordance with the manufacturer's instructions.

7.4 Carry out a disinfecting and decalcification cycle for the AWD in accordance with the manufacturer's instructions.

7.5 When replacing the cleaning solution (manual cleaning with a brush), the bowl must be thoroughly cleaned and mechanically disinfected.

7.6 Used brushes must be cleaned in an ultrasound bath, rinsed, disinfected, rinsed and dried after each use.

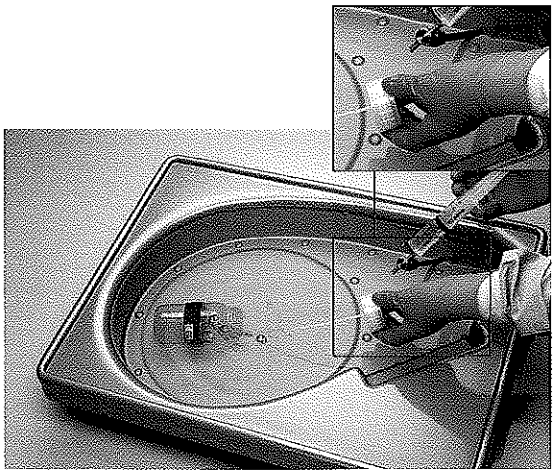
7.7 Only disinfect accessories (biopsy forceps, brushes etc.) in the AWD in accordance with the manufacturer's instructions.

Reprocess of accessories

Manual reprocessing steps for multi-use medical appliances such as biopsy forceps, polypectomy slings, papillotome/ERCP catheters, foreign body alligator forceps, water tank etc.

1. Cleaning:

- Clean accessories with soft cloth/brush, disassemble, and use a non-foaming cleaning solution. Change the solution daily or more frequently if visibly contaminated. Clean all cavities and channels under water.
- Cleaning the water tank with the CA-01T cleaning adapter.



WT-2

2. Ultrasound bath:

- The ultrasound bath should be sufficiently large and deep to ensure complete immersion. Avoid dead space and do not overload.
- A cleaning solution and a temperature of approx. 30°C should be used in the ultrasound bath (residence time: 5-10 minutes). At higher temperatures there is the risk of protein coagulation/protein fixing.
- Fix the biopsy forceps and polypectomy slings with a clip in accordance with the manufacturer's instructions and in addition hold open the branch of the biopsy forceps with another clip. When rolled up the instruments should not exceed a diameter of approx. 30 cm. Fill all the channels and cavities with solution.
- Clean for 5-15 minutes at 40 kHz in the ultrasound bath.

⚠ Comply with the manufacturer's instructions.

3. Rinsing:

- Rinse all channels and cavities with water and blow through with a compressed air gun.

4. Disinfection:

- Disinfection options for the accessories in accordance with RKI guidelines:
  - chemically with a virucidal product
  - thermo-chemically in the AWD with a virucidal product at a temperature of 35°C - 59°C
  - thermally in the AWD (Automatic Washer Disinfector) with an A0 value of 3000, i.e. at 90°C and a residence time of 5 minutes.

5. Neutralisation:

- Neutralisation/clear rinsing to remove residues of the disinfecting agent.

6. Drying:

- Drying of all channels with compressed air gun and functional test.

7. Sterilisation:

- Steam sterilisation
- Sterilisation in sterile goods packaging in a class B autoclave with fractionated pre-vacuum process.
- Dwell time for the gentle programme is 15 minutes at 121°C and 1 bar (just for FTS accessories).
- Dwell time for the universal programme is 5 minutes at 134°C and 2 bar.
- Dwell time for the prion programme is 60 minutes at 134°C and 2 bar.

⚠ Comply with the manufacturer's instructions.

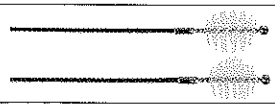
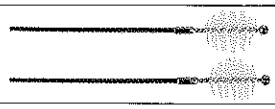
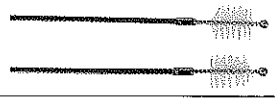
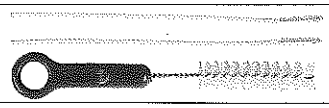
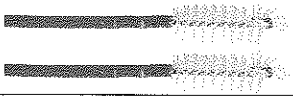
8. Storage:

- Store dry and in the dark.

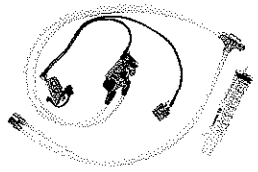
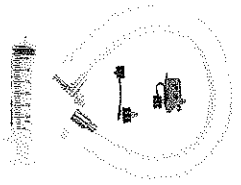
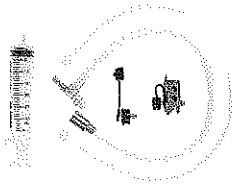
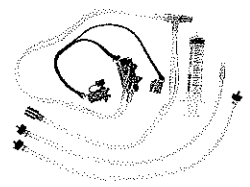
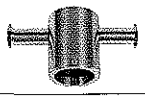
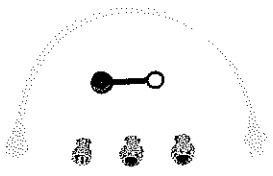
9. Function test:

- Test the function again before using with a patient.

Cleaning brushes

	Item Number		Type	Description
Reusable brushes				
1	F5RDPK1950230F		Double cleaning brush for channels with a diameter from 2.3 mm	Colonoscope
2	F5RKPK1950230F		Cleaning brush for channels with a diameter from 2.3 mm	Colonoscope
3	F5RDPK1950180F		Double cleaning brush for channels with a diameter from 2.3 mm	Gastroscope/duodenoscope
4	F5RKPK1950180F		Cleaning brush for channels with a diameter from 2.3 mm	Gastroscope/duodenoscope
5	F5RDPK1630120F F5RDPK1630180F F5RDPK1630230F		Double cleaning brush for channels with a diameter up to 2.2 mm Length: 120/180/230 cm	Endoscopes with thin diameter
6	F5RKPK1630120F F5RKPK1630180F F5RK PK1630230F		Double cleaning brush for channels with a diameter up to 2.2 mm Length: 120/180/230 cm	Endoscopes with thin diameter
7	F5RKPU1020180F F5RKPU1020230F		Cleaning brush Length: 180/230 cm	Air/water channel in series G8
8	F5VDPK0812007		Double valve cleaning brush	Valve brush for suction and air/water valves and valve supports in series G5/G8
9	F5VKPK1245012		Valve brush	Valve brush for suction and air/water valve supports in series type 3
10	F5VKPK1620013		Valve brush	Valve brush for biopsy channel inlet supports in series type 3
Disposable brushes				
11	KTE-004		Brush set	Channels with a diameter up to 2.2 mm
12	DEC-18250		Double cleaning brush	Channels with a diameter up to 2.8 mm
13	BNO-18230		Cleaning brush	Channels with a diameter up to 2.8 mm
14	DEC-17250		Double cleaning brush	Channels with a diameter up to 2.2 mm
15	BLP-10040		Valve brush	All endoscopes

Adapters

	Item Number		Type	Description
16	CA-503A		Channel cleaning set	Manual reprocess for series type 3/G5/G8
17	CA-500B		Channel cleaning set	Manual reprocess for bronchoscopes EB-470 and EB-270
18	~~CA-500C~~ CA-300C		Channel cleaning set	Manual reprocess for bronchoscopes EB-450 and EB-250
19	CA-500D		Channel cleaning set	Manual reprocess for series G5/G8 double-channel endoscopes
20	CA-300N		Cleaning adapter	Series type 3 air/water channel
21	CA-500N		*Cleaning adapter*	*Series G5/G8 air/water channel*
22	WA-500		Guide for cleaning brush	Series G8 air/water channel
23	CA-01T		Cleaning adapter	Water tank
24	CJ-500		Cleaning adapter	Series G5/G8 jet channel
25	AJ-500		Adapter with return valve	Series G5/G8 jet channel
26	JET-500		Jet channel adapter set	Series G5/G8 jet channel

General information regarding reprocess

The market for the reprocess of endoscopes provides a number of semi-automatic machine solutions in addition to machine solutions. However, to list each individual process at this point would go beyond the scope of this brochure. Fujinon would be happy to provide you with comprehensive and individually-tailored advice.

Various products have proved their worth for cleaning and disinfection. The table on the right-hand side shows these individually. Please obtain from your chemicals manufacturer the corresponding product liability declaration.

In general, products based on different active ingredients are not to be used in a reprocess cycle. This is because insufficient intermediate rinsing can result in chemical reactions such as discolouration of the outer surface or to closure of the endoscope channels.

Frequently changing the active ingredient can also have a disadvantageous effect on material compatibility. Increased wear and tear of the materials would be the result.

When changing chemicals from aldehyde to aldehyde-free products, or vice versa, ensure there is a sufficient cleaning and rinsing phase of 1-3 hours.

Compatible products create optimum conditions for manual and machine reprocess. The ideal situation would be that all products come from one manufacturer, i.e. products for preliminary cleaning in the examination room, manual cleaning of brushes, manual and machine disinfection of the endoscopes and also in the ultrasound bath for the accessories.

Examples:

- For manual preliminary cleaning/brush cleaning, use an aldehyde-free product, for example glucoprotamine. For manual/machine disinfection, use a product based on glutaraldehyde. Result: insufficient intermediate rinsing can lead to chemical reactions.
- In the ultrasound bath, use an aldehyde-free product to clean and disinfect and in the AWD use glutaraldehyde. If the different solutions enter the same escape tube at the same time, this can lead to chemical reactions and to closure of this escape tube.
- If the AWD operates with glutaraldehyde, in the event of the machine malfunctioning (repair, maintenance) a product based on glutaraldehyde should also be used for short-term disinfection. With manual disinfection with aldehyde-free products, familiar problems could arise.

Useful tips

For the protection of staff:

- Avoid risks of infection! For this reason, when carrying out manual reprocess always wear eye protection, long tear-proof gloves (vinyl) and a waterproof apron – possibly even a mask. Ideal: long-sleeved protective gown and long gloves.
- Always ensure the reprocess room has a sufficient supply of fresh air.
- Pay attention to the unclean and clean side. Caution: risk of contamination!

For reprocess in general:

- Carefully brush all channels.
- Use cleaning adapters/syringes for additional channels.
- Always clean, disinfect and dry the jet channel, lens rinsing channel, air- and water- supply channel.
- Reprocess endoscopes which have not been used for a long time since first used. Periods of time are to be specified.
- Never use an endoscope on a patient straight from its case. Always reprocess thoroughly before using.
- Regularly disinfect endoscope cabinets. Caution: disinfection periods must be specified!

List of cleaning and disinfection agents

Manual and machine reprocess with aldehydic products

Company	Manual reprocess		Machine reprocess		
	Pre-cleaning/ cleaning	**Disinfection**	**Pre-cleaning/ manual cleaning**	**Cleaning**	**Disinfection**
Bode	Bodedex forte tenside cleaner	Korsolex extra glutaraldehyde	Bodedex forte tenside cleaner	Korsolex Endo-Cleaner combination/enzyme/ tenside	Korsolex Endo-disinfectant glutaraldehyde
Schülke & Mayr	Gigazyme enzyme cleaner	GigaseptFF aldehyde	Gigazyme enzyme cleaner	Thermosept ER combination/enzyme/ tenside	Thermosept ED glutaraldehyde
Ecolab	Sekusept cleaner tenside cleaner	Sekucid Konz aldehyde	Sekusept cleaner tenside cleaner	Olympus Cleaner ETD combination/enzyme/ tenside	Olympus disinfectant ETD glutaraldehyde
Ecolab	Sekusept cleaner tenside cleaner	Sekucid N aldehyde	—	—	—
Dr. Deppe	Instru Zym enzyme cleaner	Instru Plus aldehyde formulation	Instru Zym enzyme cleaner	Labomat E enzyme cleaner	Endomat Plus aldehyde formulation
Dr. Weigert	neodisher mediclean forte, alkaline, tenside containing	neodisher Septo 3000 glutaraldehyde	neodisher mediclean forte, alkaline, tenside containing	neodisher mediclean forte alkaline, tenside containing	neodisher Septo DN aldehyde formulation

Manual and machine reprocess with products based on peracetic acid

Company	Manual reprocess		Machine reprocess		
	Pre-cleaning/ cleaning	**Disinfection**	**Pre-cleaning/ manual cleaning**	**Cleaning**	**Disinfection**
Ecolab	Sekusept® aktiv peracetic acid	Sekusept® aktiv peracetic acid	Sekusept® aktiv peracetic acid	Olympus EndoDet enzyme cleaner	Olympus EndoDis peracetic acid Olympus EndoAct activator
Ecolab	Seku Zyme enzyme cleaner	Sekusept® Easy peracetic acid	—	—	—
Dr. Weigert	—	—	neodisher mediclean forte, alkaline, tenside containing	neodisher mediclean forte alkaline, tenside containing	neodisher Septo PAC peracetic acid

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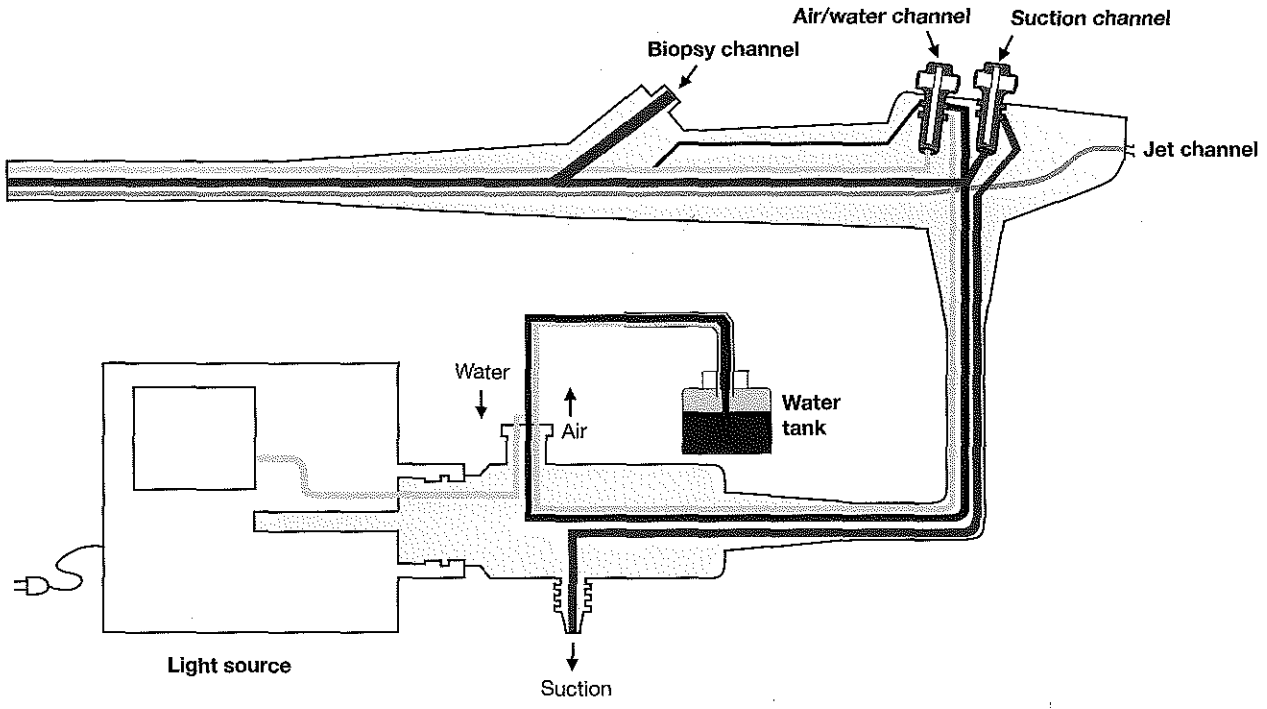
Reprocess of flexible endoscopes in practice

Series G5/G8 channel diagram



Specifications are subject to change without notice. 06/07

FUJINON (EUROPE) GMBH, HALSKESTRASSE 4, 47877 WILLICH, GERMANY, TEL.: +49 (0) 21 54 9 24-0, FAX: +49 (0) 21 54 9 24-290, www.fujinon.de
FUJINON CORPORATION, 1-324 UETAKE, KITAKU, SAITAMA CITY, 331-9624 SAITAMA, JAPAN, TEL.: +81 (0) 48 668 21 53, FAX: +81 (0) 48 668 15 70, www.fujinon.co.jp